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EXAMINER

CUTLIFF, YATE KAI RENE

ART UNIT

PAPER NUMBER

1621

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/511,829 | Applicant(s) SUMIDA ET AL. | |
| | Examiner YATE' K. CUTLIFF | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 10, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7-21 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) 8-14,19,20 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,15-18,21,24-27 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/4/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1, 4, 5, 7, 15-18, 21, 24-27 and 29-32 are pending.
Claims 2, 3, 6, 22 and 23 have been canceled
Claims 8-14, 19, 20 and 28 have been withdrawn.
Claims 1, 4, 5, 7, 15-18, 21, 24-27 and 29-32 are rejected.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 21, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Vincent et al. (Archives Internationales de, 1988).
4. The rejected claims cover, inter alia, an astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 12 carbon atoms, and the medium-chain fatty acid ester has an even number of carbon atoms.

The rejected claims cover, inter alia, composition comprising an astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 12 carbon atoms produced by using a lipase; the medium-chain fatty acid ester has an even number of carbon atoms; and is in the composition in an amount of at least 0.1%.

Vincent et al. discloses an astaxanthin monoester of lauric acid (C12:0). (see Table II). The fatty acid monoester of astaxanthin is found in the ovary of *P. schmitti* (white shrimp) during ovarian maturation. The amount of astaxanthin monoester of lauric acid is 0.9%.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 21 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vincent et al. (Archives Internationales de, 1988) in view of Hirschberg et al (US 5,965,795).

9. The rejected claims cover, inter alia, a composition of an astaxanthin medium-chain fatty acid monoester where the medium-chain fatty acid has 8 to 12 carbon atoms; or a composition that is a food composition, a food additive, a cosmetic, or an animal feed mixed with the astaxanthin medium-chain fatty acid ester.

Vincent et al. discloses a Vincent et al. discloses an astaxanthin monoester of lauric acid (C12:0). (see Table II). Vincent et al. fails to disclose that the astaxanthin monoester of lauric acid (C12:0) mixed with a food composition, a food additive, a cosmetic or an animal feed.

However, Hirschberg et al. discloses that it is astaxanthin is a principal carotenoid pigment of salmonids and shrimps. Additionally, Hirschberg et al. teaches that it is known to use astaxanthin in a mixture for feed, coloring for the food industry and cosmetics industry and a food additive for human. (see column 14, lines 19-21 & 42-52).

Applicant is reminded that the test for obviousness is what the combined teachings of those references would have suggested to those of ordinary skill in the art. In this case, Vincent et al. teaches an astaxanthin medium-chain fatty acid ester of a

shrimp and Hirschberg et al. discloses that astaxanthin a carotenoid pigment from shrimp, is utilized as feed, in food compositions, cosmetics and as food additive.

Because Vincent et al. teaches the astaxanthin medium-chain fatty acid ester and Hirschberg et al. teach that astaxanthin from shrimp is used in compositions of feed, in food compositions, cosmetics and as food additive, it would have been obvious to one skilled in the art to take the medium-chain ester from Vincent et al and use it in other known compositions that use similar astaxanthin esters.

Therefore, the rejected claims would have been obvious because a simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

10. Claims 1, 4, 5, 7, 15-18, 21, 24-27 and 29-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (US 6,265,450).

11. The rejected claims cover, inter alia, a medium The rejected claims cover, inter alia, composition comprising an astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 12 carbon atoms; the medium-chain fatty acid ester has an even number of carton atoms; and is in the composition in an amount of at least 0.1%. Additonally, the rejected claims cover , a composition of an astaxanthin medium-chain fatty acid monoester with the medium-chain fatty acid having 8 to 12 carbon atoms; or a composition that is a food composition, a food additive, a cosmetic, or an animal feed mixed with the astaxanthin medium-chain fatty acid monoester.

12. Asami et al. discloses, an anti-stress composition having as its active ingredient esters of astaxanthin including monoesters of saturated fatty acids. (see column 6, lines 28-30). The astaxanthin ester of Asami et al. can be used in the form of a pharmaceutical, cosmetic, functional food, nutritional supplement and beverage or food. (see column 7, lines 1-4). Additionally, in the food or beverage Of the Asami et al. invention, the astaxanthin ester can have a blended concentration of 0.001 to 10%. (see column 8, lines 4-10).

Asami et al. fails to specifically disclose that the astaxanthin mono-ester includes a medium-chain fatty acid with 8 to 12 carbon atoms. However, Asami et al. substantially discloses the claimed astaxanthin medium-chain fatty acid monoester in that it teaches that any monoester of a saturated fatty acid is operable in their anti-stress composition.

The difference between Asami et al. and the claimed invention is that it does not teach the invention with particularity so as to amount to anticipation (See M.P.E.P. §2131: "[t]he identical invention must be shown in as complete detail as is contained in the ...claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).).

However, based on the above, Asami et al. teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be prima facie obvious to one of ordinary skill (the

prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success. See M.P.E.P. § 2143).

Response to Amendment

13. The Amendment to claims 1, 4, 7, 21 and 27 is acknowledged and entered.

Response to Arguments

Election Restriction

14. Applicant's original election with traverse of Group I, claims 1-5, 7, 15-18, 21-27 and 29-32 in the reply filed on September 13, 2007 is acknowledged. The traversal is on the ground(s) that there is unity between the product and the process adapted to manufacture of the product. This was not found persuasive because claims 1 and 21 did not avoid the prior art of Kamat et al.

Applicant request withdrawal of the restriction requirement in the response filed on March 10, 2008, based on the amendment to claims 1 and 21, which are now directed to an astaxanthin medium-chain fatty acid monoester. The request is based on the Kamata's failure to teach the monoester. However, based Applicant's amendment Claims 1 and 21 are not rejected under 102(b) as being anticipated by Vincent et al. (Archives Internationales de, 1988). Additionally, claims 1, 4, 5, 7, 15-18, 21, 24-27 and 29-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (US 6,265,450). Therefore, Applicant's new arguments are not found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

15. The information disclosure statement (IDS) submitted on April 4, 2008 was in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

16. The drawings were received on March 10, 2008. These drawings are acceptable.

Claim Rejections - 35 USC § 112

17. Applicant's arguments, see paragraph 7, filed March 10, 2008, with respect to Claims 3, 4, 7 and 23-25 have been fully considered and are persuasive. The 112 second paragraph rejection of 3, 4, 7 and 23-25 has been withdrawn.

Claim Rejections - 35 USC § 102(b) and 103(a)

18. Applicant's arguments, see paragraph 8, filed March 10, 2008, with respect to the rejection(s) of claim(s) 1-5, 7, 18, 21-26, 27 and 32 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn due to the amendment to claims 1 and 21 and 27 which requires the astaxanthin medium-chain fatty acid ester to be a monoester. However, upon further consideration, a new ground(s) of rejection of Claims 1, 4, 21, 24 and 26 is made in view Vincent et al. (Archives Internationales de, 1988) as set out above in paragraph 2; and claims 1, 4, 5, 7, 15-18, 21, 24-27 and 29-32 in view of Asami et al. (US 6,265,450), set out above in paragraph 11.

19. Applicant's arguments, see paragraph 9, filed March 10, 2008, with respect to the rejection(s) of claim(s) 7, 15-17, 21; and 27 and 29-32 (15-17 as listed was typographical error) under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn due to the amendment to claims 1 and 21 and 27 which requires the astaxanthin medium-chain fatty acid ester to be a monoester. However, upon further consideration, a new ground(s) of rejection of Claims 21 and 15-18 is made in view Vincent et al. (Archives Internationales de, 1988) in view of Hirschberg et al. (US 5,965,795) as set out above in paragraph 9.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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